MAY 2 3 2003

K031217
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11mm GMRS Press Fit Stem with PureFix® HA
510(k) Premarket Notification - Labeling Change Being Effected

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

Device Identification

Proprietary Name:	GMRS Press Fit Stems with PureFix® HA
Common Name:	Modular Stem
Classification Name and Reference	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis {tc \l3 "Classification Name and Reference}
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) LZO

Intended Use

The Global Modular Replacement System (referred to from this point on as the GMRS) Press Fit Stems with PureFix® HA Coating were found substantially equivalent in premarket notification K022403. These stems are intended to be used with components of the proximal femoral segment of the Howmedica Modular Replacement System (referred to from this point on as the MRS) in total hip arthroplasty. These devices are intended for use in total hip arthroplasty indicated as a result of extensive proximal femoral bone loss (from trauma, failed previous arthroplasty, or tumor resection).

Adequate bone stock must be present to allow the use of the GMRS Press Fit Stems with PureFix® HA Coating.

Indications

Proximal femoral reconstruction secondary to:

- Trauma
- Failed previous prosthesis
- Tumor resection

Contraindications

- Overt infection
- Rapid disease progression beyond an acceptable margin

For the use of GMRS Press Fit stems with PureFix® HA Coating, the following additional contraindication should be noted:

- Inadequate bone stock to allow the use of a press fit stem

The purpose of this premarket notification is to add a warning to the package label for the 11mm GMRS Press Fit Stems with PureFix HA. This warning puts a weight limitation on the patient in which the stem is being implanted. The package insert advises the user to refer to the package label for additional information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Ms. Margaret Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401

Re: K031217
Trade/Device Name: 11mm GMRS Press Fit Stem with PureFix® HA (Labeling Change Being Effected)
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: April 16, 2003
Received: April 17, 2003

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

11mm GMRS Press Fit Stem with PureFix® HA
510(k) Premarket Notification - Labeling Change Being Effected

510(k) Number (if known): K031217

Device Name: 11mm diameter GMRS Press Fit Stems with PureFix® HA

Intended Use

The Global Modular Replacement System (referred to from this point on as the GMRS) Press Fit Stems with PureFix® HA Coating are intended to be used with components of the proximal femoral segment of the Howmedica Modular Replacement System in total hip arthroplasty. These devices are intended for use in total hip arthroplasty indicated as a result of extensive proximal femoral bone loss (from trauma, failed previous arthroplasty, or tumor resection). Adequate bone stock must be present to allow the use of the GMRS Press Fit Stems with PureFix® HA Coating.

The 11mm diameter GMRS Press Fit Stems with PureFix® HA will bear a weight limitation on the label. The 11mm stems will be limited to use in patients with a maximum weight of 199 lbs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031217